

REMARKS

Claims 68, 138 and 142-186 are pending in the instant application. No amendments have been made to the claims or specification. Accordingly, claims 68, 138 and 142-186 will remain pending in the application. No new matter has been added.

Amendment and cancellation of the claims at any time during the prosecution of this application are not to be construed as acquiescence to any of the objections/rejections set forth in the instant Office Action or any previous Office Action, and are done solely to expedite prosecution of the application. Applicants submit that claims were not added or amended during the prosecution of the instant application for reasons related to patentability. Applicants reserve the right to pursue the claims as originally filed, or similar claims, in this or one or more subsequent patent applications.

Claim Rejections - 35 U.S.C. §102***Rejection of Claims 138 and 142-145 under 35 U.S.C. §102(b)***

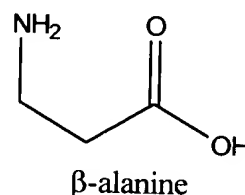
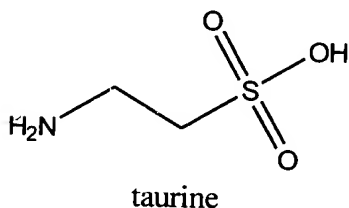
Claims 138 and 142-145 are rejected under 35 U.S.C. §102(b) as anticipated by Fariello *et al.*, U.S. Patent No. 4,255,448. In particular, the Office Action states that the patent discloses that ω -amino acids such as β -alanine, taurine, etc. possess anticonvulsant effects and therefore, are useful as therapeutic agents for convulsive disorders. The Office Action further states that the instant claims read on the prior art taught therapeutic effect because the instant claims are drawn to administration of the *prior art compounds*, *e.g.*, β -alanine and taurine.

Applicants respectfully traverse this rejection. Applicants refer the Examiner to column 1, lines 18-22 of Fariello *et al.*, which discloses that it is well established based on the prior reference of Krnjevic, K. (1974. Chemical nature of synaptic transmission in vertebrates. *Physiol. Rev.* 54; 418-540) that “naturally occurring, short chain ω -amino acids such as glycine, β -alanine, GABA, and taurine all possess powerful inhibitory actions at various levels within the mammalian central nervous system.” Furthermore, Fariello *et al.* merely asserts that the “demonstration of an

anticonvulsant effect after systemic administration is an essential prerequisite for possible therapeutic application,” and describes a “series of tests” that were performed only on specific ω -amino acids.

Applicants submit that this statement in Fariello *et al.* does not disclose that **all** ω -amino acids possess anticonvulsant activity, nor does it state that ω -amino acids other than the ω -amino acids indicated in column 1, lines 32-36, (*i.e.*, gamma aminobutyric acid (GABA), 3-aminopropane sulfonic acid (3-APS), taurine (TAU), and β -alanine (BALA)) have even been investigated for anticonvulsant activity. As such, the compounds associated with possible anticonvulsant activity by Fariello *et al.* are not the entire class of ω -amino acids, as suggested on page 3 of the Office Action.

For the Examiner's convenience, the structures of taurine and β -alanine are shown below:



Both of these compounds of the Fariello *et al.* reference would be considered by the ordinarily skilled artisan as **unsubstituted** β -amino anionic compounds (as defined by the instant specification).

Applicants submit that claims 138 and 142-145 are directed to “**substituted** β -amino anionic compounds” and **not unsubstituted** β -amino anionic compounds. Moreover, the ordinarily skilled artisan would have understood that the claims of the instant application, which are directed to substituted β -amino anionic compounds as defined on page 14, lines 21-31 of the specification, are characterized by the replacement of at least one H by, for example, one of the possible substituents noted in the specification. For example, in the specification, on page 15, lines 14-16, the term “substituted” as used, for example, in the language “substituted alkyls,” refers to alkyl moieties having substituents replacing a hydrogen on one or more carbons of the hydrocarbon backbone. From the above-depicted structures, it can be clearly seen that neither taurine nor β -alanine falls

within the scope of the claimed **substituted** β -amino anionic compounds, as there are no hydrogens in the β -amino anionic compounds shown that have been replaced by substituents.

Applicants submit that the ω -amino acids described in Fariello *et al.*, such as taurine and β -alanine, would not have been considered by the ordinarily skilled artisan to be *substituted* β -amino anionic compounds nor do they fall within the scope of the term “substituted,” as used in the instant specification. Therefore, Applicants submit that Fariello *et al.* does **not** anticipate claims 138 and 142-145, and respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claims 138, 142, 143, and 145 under 35 U.S.C. §102(b)

Claims 138, 142, 143, and 145 are rejected under 35 U.S.C. §102(b) as anticipated by Huxtable *et al.*, CAPLUS Abstract 89:70974. In particular, the Office Action states that the reference discloses that taurine produces anticonvulsant effects and decreases the susceptibility of seizures. Moreover, the Office Action states that the “instant claims read on the reference disclosed therapeutic effect because the instant claims are drawn to administration of the reference disclosed compound to achieve the same effect.”

Applicants respectfully traverse this rejection and refer the Examiner to the arguments presented above in response to the rejection of claims 138, 142, 143, and 145 under 35 U.S.C. §102(b) as anticipated by Fariello *et al.*, and hereby incorporate those arguments herein. Applicants respectfully point out that claims 138, 142, 143, and 145 are directed to “**substituted** β -amino anionic compounds.” Moreover, taurine would not have been considered by the ordinarily skilled artisan to be a *substituted* β -amino anionic compound of the invention. Therefore, in contrast to the statement made in the Office Action on page 3, the claims of the invention would not “read on the reference disclosed therapeutic effect,” because the instant claims are **not** drawn to the “administration of reference disclosed compounds.”

Therefore, in view of the foregoing arguments, Applicants submit that the Huxtable *et al.* reference does **not** anticipate claims 138, 142, 143, and 145, and respectfully request reconsideration and withdrawal of the rejection.

***Provisional Rejection of Claim:
Judicially Created Doctrine of Obviousness-Type Double Patenting***

Provisional Rejection of Claim 68, 138 and 142-153 under Judicially Created Doctrine of Obviousness-Type Double Patenting

Claims 68, 138 and 142-153 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 68-90 of U.S. Application No. 09/932,676. In this regard, Applicants will address the obviousness-type double patenting rejection upon a finding that the claims are in condition for allowance but for the obviousness-type double patenting rejection.

CONCLUSION

In view of the foregoing remarks presented, favorable reconsideration and withdrawal of the rejections, and allowance of this application with all pending claims are respectfully requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is invited to call the undersigned at (617) 227-7400.

Respectfully submitted,

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